

23 November 2021

Jai Ganesh

By email: fyi-request-17519-7365473a@requests.fyi.org.nz

Ref: H202115965

Dear Jai

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 11 November 2021 for information regarding the COVID-19 vaccine. Each part of your request is responded to below.

*What are the particular clinical trials referred to here: <https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-clinical-trials-and-testing#participants>
What are the particular ongoing clinical trials that are being referred to?*

The trials the Ministry is referring to on the website are the clinical trials ran by Pfizer. Medsafe continues to receive information from Pfizer about the trials while the vaccine is under provisional approval. You can find details for the trials at: clinicaltrials.gov/

What metrics is Medsafe looking at from the overseas rollouts? Do they take into consideration adverse events? If so, how come Takata can recall 30M airbags after 30 deaths but Medsafe cannot?

In New Zealand, there has only been one death linked to vaccination with the Pfizer Comirnaty COVID-19 vaccine, which has been referred to the coroner for determination. However, there have been 34 deaths from the COVID-19 infection.

These questions are based on a misunderstanding of pharmacovigilance and the reporting of adverse events following immunisation (AEFI). Medsafe publishes regular reports about AEFI, including analysis of deaths. You can find the reports here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp. You may also find the Annenberg Public Policy Centre's response to similar questions helpful: www.factcheck.org/2021/11/scicheck-why-its-easy-to-misinterpret-numbers-of-deaths-among-the-vaccinated/.

*What is the process Medsafe follows when it comes to vetting medicines?
Does Medsafe conduct independent tests of their own or do they take the manufacturer's word for it?*

Information about Medsafe's approval processes for medicines and vaccines can be found at: medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

Who is the Independent Data Monitoring Committee being referred to?

There is no Independent Data Monitoring Committee. I have interpreted your question to refer to the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB). CV-ISMB are a panel of experts, independent from manufacturers and government officials, who review safety data for COVID-19 vaccines in New Zealand.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe